

### REMARKS

By the present Amendment, the applicants have amended the claims by cancelling claims 13 and 14 and amending claims 11, 12, 15, 16, 18 and 20 in order to overcome the 35 U.S.C. 112, second paragraph, objections.

In the Office Action, the Examiner indicated that the attorney of record must make certain statements as to the availability to the public of the microorganisms recited in the claims.

The undersigned, an attorney of record herein, states that the two (2) strains of *Bifidobacterium longum* named W11 and W11a in the application, deposited under the terms of the Budapest Treaty at the Belgium Coordinated Collection of Microorganisms (BCCM) that have been registered under the Accession numbers LMG P-21586 and LMG P-21587 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

In the Office Action, the Examiner rejected claims 11 to 26 as being anticipated by or in the alternative, obvious over U.S. Patent No. 6,783,780, to *De Jong et al*, granted August 31, 2004. The Examiner maintains that the *De Jong et al* reference teaches strains of *Bifidobacterium longum* and probiotics containing them and that therefore it anticipates the present invention. The applicants point out that the biologically pure strains of *Bifidobacterium longum* disclosed and claimed in the present application are not disclosed or even hinted at in the *De Jong et al* reference. In fact, *Bifidobacterium longum* is only generally referred to in the cited patent as being one of the *Bifidobacterium* strains which can be used in the invention disclosed therein. The

only specific strain of microorganism disclosed in *De Jong et al* is *Lactobacillus rhamnosus* ATCC 7469 which is described in Examples I and VI.

As clearly stated in the specification at page 3, lines 14 to 21, the specific strains claimed herein were "selected among many other strains of *Bifidobacterium longum* contemporaneously isolated because they have shown a colonizing capability on the intestinal cells, characteristics that both make them very good probiotic agents able to help the good health of the gastrointestinal tract and to restore its altered functionality from gastroenteritis of various origin."

Furthermore, bacterial cultures of the *Bifidobacterium longum* strains of the present invention have been checked in colonization tests of the intestine of mice with positive results as indicated in the specification at page 4, lines 15 to 26. Also, stability tests have shown that the strains have an extremely good resistance to change at room temperature and a shelf life of two years after manufacture, as stated in the specification at page 6, lines 22 to 25.


The object of the present invention is to enrich the range of available strains and provide *Bifidobacterium longum* strains that are able to reach the intestinal mucosa in such a number and with such a vitality after ingestion, that they are able to persist and to colonize the intestine. This objective is satisfied by the strains of the present invention. The *De Jong et al* reference does not disclose a *Bifidobacterium longum* strain that is capable of colonizing the digestive tube of mice with human flora. There is

nothing in the *De Jong et al* reference which gives an incentive to one skilled in the art to attempt to isolate *Bifidobacterium longum* in order to arrive at strains which solve the underlying problem of reaching the intestinal mucosa, after passing through the stomach, in such numbers and with such vitality that they are able to persist and to colonize the intestine.

In view of the above, it is respectfully submitted that claims 11, 12 and 15 to 26 are not anticipated by, nor rendered obvious in view of, U.S. Patent No. 6,783,780, to *De Jong et al*, and that therefore the rejection of these claims should be withdrawn and the claims allowed. Such action is respectfully solicited.


Respectfully submitted,

CLAUDIO VISCOMI, ET AL

BY:   
Joseph J. Orlando, Reg. No. 25,218  
Attorney for Applicant

BUCKNAM AND ARCHER  
CUSTOMER No.: 178  
1077 Northern Boulevard  
Roslyn, NY 11576  
516 365-9802

I hereby certify that this document is being deposited with the U.S. Postal Service on March 14, 2005, as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Maria Guastella